



UNITED STATES PATENT AND TRADEMARK OFFICE

m. H

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,579	12/20/2000	Vahid Saadat	VAA-004	1598

1473 7590 05/09/2003
FISH & NEAVE
1251 AVENUE OF THE AMERICAS
50TH FLOOR
NEW YORK, NY 10020-1105

EXAMINER

IZAGUIRRE, ISMAEL

ART UNIT PAPER NUMBER

3765

DATE MAILED: 05/09/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/746,579

Applicant(s)

SAADAT, VAHID

Examiner

Ismael Izaguirre

Art Unit

3765

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20,21 and 55-65 is/are allowed.
- 6) ☒ Claim(s) 1-8,10-14,18,19,22-32 and 35-54 is/are rejected.
- 7) ☒ Claim(s) 15-17,33 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 3765

DETAILED ACTION

The Examiner is appreciative of the changes made to the language of the claims. These have been duly noted and considered.

CLAIMS

Summary

Claims 1,18,20,22,35,41,47,55 and 60 are the independent claims under consideration in this Office Action.

Claims 2-8,10-17,19,21,23-34,36-40,42-46,48-54,56-59 and 61-65 are the dependent claims under consideration in this Office Action.

Claim 9 has been canceled.

Claim Patentability

Concerning the Patentability of the claims, the following is submitted for Applicant's consideration:

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3765

Claims 1-3,8,10-14,18,22,26-32,35,38-41,44-47 and 50-54 are rejected under 35 U.S.C. § 102(b) as being anticipated by Vargas et al. (6,428,550).

Vargas et al. teach an apparatus for closing a wound. Vargas et al. teach an elongated substrate 120 or 200 (figures 12, 13 and 25-38, for example) formed of a biocompatible material, such as Nitinol (column 11, line 18) having a first tissue facing surface and a second tissue facing surface. A multiplicity of barbs 206, 212 (figure 26, for example) are provided projecting from at least one tissue facing surface and specifically from the two tissue facing surfaces (figures 23 and 24, for example). The multiplicity of barbs being formed by cutting these from the substrate.

The substrate with barbs can be shaped into a tube or stent-like structure having interior and exterior surfaces for providing a side anastomosis of a tissue. Further, The substrate includes a plurality of perforations (between diamond shaped linkages 204 passing from the first surface to the second surface. The barbs are taught as including a shank portion with a tissue penetrating distal end and one or more projections from the shank. See figures 25 for barbs 212 and figure 27 for barbs 206'. The barbs and perforations form units repeatable in pattern and interconnecting the pattern units by joints or linkages, such as at the linkages 226, figure 28.

The device is used for closing a tissue wound by placing the device within the wound and directing the barbs toward a tissue engaging position and squeezing the tissue about the barbs so as to hold the wound closed by the substrate. In this case closing the wound of a vessel by the insertion of another graft vessel.

Art Unit: 3765

Claims 1,6,10,12,13,18,19,22,25,28,30,31,41,43,45-47,49,51,52 and 54 are rejected under 35 U.S.C. § 102(b) as being anticipated by Williams (5,423,885).

Williams teaches an apparatus for closing a wound. Williams teaches an elongated substrate (figure 1, for example) formed of a biocompatible material, such as Nitinol (column 3, lines 15-29) having first and second surfaces. A multiplicity of barbs 15 are provided projecting from at least one tissue facing surface 5. The multiplicity of barbs being formed by cutting these from the substrate (column 2, lines 51-54). The substrate with barbs can be shaped into a tube or stent-like structure having interior and exterior surfaces for providing a side anastomosis of a tissue. Further, The substrate includes a plurality of perforations formed by the space left by the cut barbs passing from the first surface to the second surface. Further, The barbs are taught as being impregnable by a therapeutic agent to provided localized drug delivery (column 4, lines 4-6).

Claims 18,19, 35,36,38,40-42,44,46-48,50, and 52-54 are rejected under 35 U.S.C. § 102(b) as being anticipated by Wholey (5,383,897).

Wholey teaches an apparatus for closing a wound. Wholey teaches an elongated substrate 2 formed of a biocompatible material (column 4, line 20) having first and second surfaces. A multiplicity of barbs 4 are provided projecting from at least one tissue facing surface. The barbs include a shank portion at the substrate surface and tissue engaging distal ends with one or more projections from the shank. The substrate with barbs can be shaped into a tube or stent-like structure having interior and exterior surfaces for providing a side anastomosis

Art Unit: 3765

of a tissue. Further, when formed into a tube the substrate with barbs is inserted within a vessel (figures 3 or 4) and is used to close the wound by allowing the squeezing of the tissue against the substrate for penetration of the barbs into the tissue, whether on an inner surface of the vessel or an outer surface of a vessel. The barbs are taught as coated with a therapeutic agent for promoting thrombogenesis at the puncture site. See column 4, lines 4-10.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3,8,10,12-14,22,26-28,31,41,44-47 and 50-52 and 54 are rejected under 35 U.S.C. § 102(a) as being anticipated by Berg et al. (WO 00/69365).

Berg et al. teach an apparatus for closing a wound. Berg et al. teach an elongated substrate (figure 27, for example) formed of a biocompatible material having a first surface (from where barbs 2714 extend from) and a second surface (from where barbs 2715 extend from). These first surfaces and second surfaces include a multiplicity of barbs 2715 and 2714 projecting therefrom. Further, when the substrate is formed into a tube (figure 28, for example) the substrate would include an external/first tissue facing surface and an interior/second instrument (2889) facing surface.

Art Unit: 3765

The barbs 2815 extend from the first tissue facing surface for penetration into the tissue (as in figure 30). The barbs further include a shank portion and distal tissue engaging portions with further projections on the shanks (figure 28, for example). Berg et al. teach a plurality of perforations passing from the first surface to the second surface and the multiplicity of barbs being formed by cutting these from the substrate. As noted above, the substrate with barbs can be shaped into a tube or stent-like structure having interior and exterior surfaces for providing a side anastomosis of a tissue and the barbs and perforations form units repeatable in pattern and interconnecting the pattern units by joints or linkages.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5,7,24,42 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams '885.

Williams discloses the invention substantially as claimed. See above for specific structural details. Briefly, Williams teaches a substrate with barbs for forming a stent-like apparatus and closing a wound. Williams teaches the substrate and barbs as being impregnable with a therapeutic agent. However, Williams does not suggest coating the substrate and barbs

Art Unit: 3765

with a therapeutic agent and that agent being selected from a family of angiogenic growth factors.

It would have been obvious to a person having ordinary skill in the art of stent forming at the time of applicant's invention to construct the device of Williams as including a coating of a therapeutic agent selected from the family of angiogenic growth factors. Providing such a coating would allow the lowering of the cost of the device since the device would be formed first and only a coating and not an impregnation of the device would suffice to provide the localized therapeutic agent delivery.

Claims 37,43 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wholey '897.

Wholey discloses the invention substantially as claimed. See above for specific structural details. Briefly, Wholey teaches a substrate with barbs for forming a tube or stent-like apparatus and closing a wound. Wholey teaches the substrate and barbs as being coated with a therapeutic agent. However, Wholey does not suggest impregnating the substrate and barbs with a therapeutic agent.

It would have been obvious to a person having ordinary skill in the art of stent forming at the time of applicant's invention to construct the device of Wholey as including an impregnation of a therapeutic agent. Providing such an impregnation would assure the slow release of therapeutic agents to the wound during the healing process. This would lower the chances of the body rejecting the device and thus speed up healing.

Art Unit: 3765

Claims 4 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. '365.

Berg et al. disclose the invention substantially as claimed. See above for specific structural details. Briefly, Berg et al. teach a substrate with barbs for forming a tube or stent-like apparatus and closing a wound. Berg et al. teach the substrate including a multiplicity of perforations for attachment of a plug therein. See figure 27, character number 2730. However, Berg et al. do not specifically suggest these attachments as including sutures and the perforations defined as suture eyelets.

It would have been obvious to a person having ordinary skill in the art of stent forming at the time of applicant's invention to construct and define the perforations of the device of Wholey as including suture eyelets for performing the connection between the stent and plug passing therethrough. Providing such attachment means would assure the immobility of the plug at its central axis. Using sutures for the connection would allow the connection of the plug in increments by the surgeon and thus precisely locate the plug.

Claims 5,6,24,25,42,43, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. '365 and further in view of Williams '885 and Wholey '897.

Berg et al. disclose the invention substantially as claimed. See above for specific structural details. Briefly, Berg et al. teach a substrate with barbs for forming a tube or stent-like apparatus and closing a wound. However, Berg et al. do not suggest impregnating or coating the substrate and barbs with a therapeutic agent.

Art Unit: 3765

Williams teaches a substrate with barbs for forming a stent-like apparatus and closing a wound. Williams teaches the substrate and barbs as being impregnable with a therapeutic agent.

Wholey teaches a substrate with barbs for forming a tube or stent-like apparatus and closing a wound. Wholey teaches the substrate and barbs as being coated with a therapeutic agent.

It would have been obvious to a person having ordinary skill in the art of stent forming at the time of applicant's invention to construct the device of Berg et al. as including a coating of a therapeutic agent as taught desirable in Williams. Providing such a coating would allow the lowering of the cost of the device since the device would be formed first and only a coating and not an impregnation of the device would suffice to provide the localized therapeutic agent delivery.

Further, it would have been obvious to a person having ordinary skill in the art of stent forming at the time of applicant's invention to construct the device of Berg et al. as including an impregnation of a therapeutic agent. Providing such an impregnation would assure the slow release of therapeutic agents to the wound during the healing process. This would lower the chances of the body rejecting the device and thus speed up healing.

Accordingly, from the above, it would have been obvious to a person having ordinary skill in the art of stent forming at the time of applicant's invention to construct the device of Berg et al. as including an impregnation or coating of a therapeutic agent upon the device.

Art Unit: 3765

Allowable Subject Matter

Claims 20,21 and 55-65 are allowable over the prior art of record.

Claims 15-17,33 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

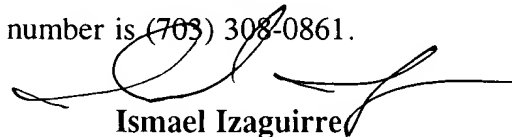
Pertinent Citations

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Esplin illustrates a substrate with barbs directed from a first surface for closing a wound. Green illustrates surgical fasteners including units connected to each other and used with cooperating halves.

INQUIRIES

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Ismael Izaguirre located in CP2-4B18 whose telephone number is (703) 308-0892. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.



Ismael Izaguirre
Primary Examiner
Art Unit 3765